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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,329	10/28/2003	David Schneider	SDR-10802/01	4848
25006	7590	07/17/2006	EXAMINER	
GIFFORD, KRASS, GROH, SPRINKLE & CITKOWSKI, P.C			DRYDEN, MATTHEW DUTTON	
PO BOX 7021				
TROY, MI 48007-7021			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 07/17/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/695,329	Applicant(s) SCHNEIDER, DAVID	
	Examiner Matthew D. Dryden	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges applicant's amendments to the claims in response to the first action submitted on April 27, 2006.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo (5910122) in view of Thieme et al (5871905). D'Angelo discloses the claimed invention except for the container having a preservative solution. D'Angelo teaches a saliva collection device (element 2 in Figure 1), the device including suction means (around element 17 in Figure 2) and an exterior surface (between elements 1 and 2 in Figure 1, also underneath element 1 in Figure 1) and having a salivation catalyst positioned on the exterior surface (element 1 is positioned on the exterior surface of the saliva collection device, see Column 5, lines 3-5 for the salivation catalyst). Thieme et al teaches it is known to provide a storage vial with a preservation solution inside to maintain the integrity and prevent contamination of the sample during transportation or analysis (see Column 11, lines 39-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of D'Angelo to include a preservative solution within the container holding the sample, as taught by Thieme et al, to maintain the integrity and prevent contamination of the sample during transportation or analysis.

Regarding claim 2, element 10 in Figure 3 is resealable.

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Regarding claim 3, see Column 5, lines 33-47.

Regarding claim 4, see element 2 in Figure 1.

Regarding claim 5, see Column 5, lines 3-5.

Regarding claims 9 and 10, see Thieme et al, lines 28-48.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo in view of Thieme et al, as applied to claim 5 above, and further in view of Aronowitz (20010008614). D'Angelo as modified discloses the claimed invention except for the flavoring being selected from a group consisting of lemon, peppermint, spearmint and orange flavorings. Aronowitz teaches it is well known in the art to provide a flavoring that includes lemon, lime, orange or the like (see Column 7, lines 2-4) to stimulate a person's saliva production. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of D'Angelo with a flavoring being selected from a group consisting of lemon, peppermint, spearmint and orange flavorings, as taught by Aronowitz, to stimulate a person's saliva production..

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Angelo in view of Thieme et al, as applied to claim 1 above, and further in view of Putcha et al (6133036). D'Angelo as modified discloses the claimed invention except for the specific solution disclosed in claim 7, comprising: sodium chloride, NaHPO_4 and NaH_2PO_4 in an aqueous concentration to provide a 50mM phosphate solution and .5-2.0 g sodium benzoate. However, the applicant provides two other preservative solutions that can also be used in the same application and device. Therefore the solution is deemed not to be a critical component of the current application and at the

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time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a preservative solution of sodium chloride, NaHPO_4 and NaH_2PO_4 in an aqueous concentration to provide a 50mM phosphate solution and .5-2.0 g sodium benzoate. Applicant has not disclosed the specifics of the solution providing an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Putcha et al's preservative solution, and applicant's invention, to perform equally well with either the solution taught by Putcha et al or the claimed solution because both solutions would perform the same function of preserving the collected sample equally well. Therefore, it would have been prima facie obvious to further modify D'Angelo to obtain the invention as specified in claims 7 and 8 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Putcha et al.

Claims 11-18, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al in view of D'Angelo. Thieme et al discloses the claimed method except for the saliva collection device disclosed in the third portion of the claim. For the method steps of Thieme et al for the method steps see Columns 7-9, lines 24-48, for collection and assaying see Columns 11-12 lines 39-41. D'Angelo teaches it is known to provide a saliva collection device (element 2 in Figure 1), the device including suction means (around element 17 in Figure 2) and an exterior surface (between elements 1 and 2 in Figure 1, also underneath element 1 in Figure 1), and having a salivation catalyst positioned on the exterior surface (element 1 is positioned on the

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exterior surface of the saliva collection device, see Column 5, lines 3-5 for the salivation catalyst), to collect saliva samples for body fluid constituent analysis (see Abstract and whole document). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Thieme et al with a saliva collection device as taught by D'Angelo, to collect saliva samples for body fluid constituent analysis and to transfer the samples from one collection tube to another while maintaining the integrity of the sample.

Regarding claim 15, Thieme et al discloses the claimed method except for the container comprising a resealable tube. D'Angelo teaches it is known to provide a resealable tube (see Column 5, lines 26-47) to allow for reopening and closing of the tube to perform multiple analyses on the sample. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Thieme et al to include a resealable container, as taught by D'Angelo, to allow for reopening and closing of the tube to perform multiple analyses on the sample.

Regarding claim 16, see Column 5, lines 43-44 of D'Angelo.

Regarding claim 17, the saliva collection device of D'Angelo comprises a transfer pipette having a compression end and an intake end (see Figures 1 and 2).

Regarding claim 18, see Column 5, lines 3-5 of D'Angelo.

Regarding claims 21 and 22, see Thieme et al, lines 28-48.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al in view of D'Angelo, as applied to claim 5 above, and further in view of Aronowitz (20010008614). Thieme et al as modified discloses the claimed invention except for the

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flavoring being selected from a group consisting of lemon, peppermint, spearmint and orange flavorings. Aronowitz teaches it is well known in the art to provide a flavoring that includes lemon, lime, orange or the like (see Column 7, lines 2-4) to stimulate a person's saliva production. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Thieme et al with a flavoring being selected from a group consisting of lemon, peppermint, spearmint and orange flavorings, as taught by Aronowitz, to stimulate a person's saliva production..

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thieme et al in view of D'Angelo as applied to claim 11 above, and further in view of Putcha et al (6133036). Thieme et al as modified discloses the claimed invention except for the specific solution disclosed in claim 7, comprising: sodium chloride, NaHPO_4 and NaH_2PO_4 in an aqueous concentration to provide a 50mM phosphate solution and .5-2.0 g sodium benzoate. However, the applicant provides two other preservative solutions that can also be used in the same application and device. Therefore the solution is deemed not to be a critical component of the current application and at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a preservative solution of sodium chloride, NaHPO_4 and NaH_2PO_4 in an aqueous concentration to provide a 50mM phosphate solution and .5-2.0 g sodium benzoate. Applicant has not disclosed the specifics of the solution providing an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Putcha et al's preservative solution, and applicant's invention, to perform equally well with either

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the solution taught by Putcha et al or the claimed solution because both solutions would perform the same function of preserving the collected sample equally well. Therefore, it would have been prima facie obvious to further modify Thieme et al to obtain the invention as specified in claim 20 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Putcha et al.

Response to Arguments

Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

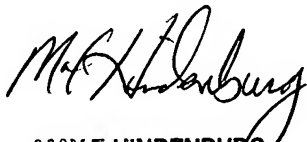
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MDD


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